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| 09/600,952 | 07/25/2000 | Edna Chosack | S02/11 | 4168 |

7590

07/17/2003

D Graeser
The Polkinghorns
9003 Florin Way
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EXAMINER

SAADAT, CAMERON

| ART UNIT | PAPER NUMBER |
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3713

DATE MAILED: 07/17/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/600,952

Applicant(s)

CHOSACK ET AL.

Examiner

Cameron Saadat

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) 1-17, 21-25, 27, 39-40, 44-45 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 26 and 41-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

In response to amendment filed 5/5/03, claims 1-27, 39-44, and newly added claim 45 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement filed 1/30/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Matsuzaki et al. (USPN 6,283,763 B1).**

Regarding claim 1, Matsuzaki discloses a simulated medical procedure comprising: a simulated organ (See Fig. 8), a simulated instrument (Col. 4, line 14), and simulated instrument locator 2; and a visual display 9 for displaying images created from actual data of an actual medical procedure (Col. 5, lines 8-12), according to location of a simulated instrument within a simulated organ (Col. 5, lines 16-21). The display further includes a three-dimensional mathematical model for modeling the simulated organ according to a corresponding actual organ; the model is divided into a plurality of segments (Col. 4, lines 54-65); the plurality of segments being arranged in a linear sequence (see Fig. 7A); and the display further includes a loader for selecting at least one of the plurality of

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segments for display according to the location of the simulated instrument and displayer 9 for displaying the simulated image (Col. 7, lines 35-43).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 2-5, 11-17, 21, 23-25, 27, 39, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. (USPN 6,283,763 B1; hereinafter Matsuzaki) in view of Gillio (U.S. Patent No. 5,882,206).**

Regarding claims 2-4, and 44, Matsuzaki discloses all of the claimed subject matter with the exception of not explicitly disclosing a *texture mapping database*. However, Gillio teaches database 104 comprising texture data (column 4, lines 63-66), wherein simulated images are overlaid with texture mapping data before being displayed (column 12, lines 64-65). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the stored images described in Matsuzaki, by providing texture mapping data. The motivation for doing so would have been to provide a more realistic simulation and greater accuracy.

Regarding claim 5, Matsuzaki discloses a system in which images are obtained by recording visual data during a medical procedure and selecting said images from the captured visual data (Col. 5, lines 8-12).

Regarding claims 11-12, Matsuzaki discloses the use of a displayer 9, but does not explicitly teach the use of a graphical user interface (as per claim 11) and does not teach a graphical user interface that displays tutorial

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information (as per claim 12). However, Gillio teaches the use of a graphical user interface (column 5, lines 27-31), and also a graphical user interface that displays tutorial information (column 3, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the displayer described in Matsuzaki, by providing a graphical user interface and tutorial information, thereby allowing a student to easily interact with the simulator and receive helpful information regarding the medical procedure.

Regarding claims 13-14, Matsuzaki discloses a simulated organ for an endoscopic procedure, but does not specify the organ as being a gastro-intestinal tract (as per claim 13) and that the organ is constructed of semi-flexible material (as per claim 14). However, Gillio teaches a simulated organ as being a gastro-intestinal tract (column 7, lines 39-43). Furthermore, Gillio teaches a simulated organ 110 comprising virtual orifice 112, and wherein the surface of the orifice is adjusted (column 7, lines 29-31; column 6, lines 64-66) with springs and rollers pressing against the orifice wall, thus providing a flexible orifice wall (See Fig. 4). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ described in Matsuzaki, by providing a simulated organ of a gastro-intestinal tract and constructing it from smooth, semi-flexible material, in order to simulate an endoscopic surgical procedure on various gastrointestinal organs, and providing realistic tactile feedback.

Regarding claim 15, Matsuzaki discloses a simulated instrument comprising a sensor 2 for determining the location of the simulated instrument within the simulated organ, and a computer 8 to provide visual feedback of the simulated instrument location.

Regarding claim 16, Matsuzaki further discloses a tactile feedback mechanism corresponding to the location of the tip of an endoscope (Col. 2, line 27; Col. 7, lines 1-7).

Regarding claim 17, Matsuzaki discloses a force reflective mechanism that provides tactical feedback on the simulated instrument, but does not specifically teach that the mechanism is contained in a gastro-intestinal tract. However, Gillio teaches a tactile feedback mechanism located in the gastro-intestinal tract comprising servo-motors, wherein the rollers 230, 232, 234, and 236 can be fitted with the servo-motors to contact the semi-flexible material of the orifice 112 of the simulated organ 110; a controller for controlling the servo-motors, such that the position of the rollers is determined by the controller in order to provide tactile feedback (column 7, lines 12-20). Although a piston is not specified, it is the examiner's position that it would have been an obvious matter of choice well within

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the capabilities of one skilled in the art to use a piston in place of the rollers described by Gillio because this feature provides no criticality with respect to the invention. Thus, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ tactile feedback mechanism described in Matsuzaki, by providing tactile feedback contained in a gastro-intestinal track. The motivation for doing so would have been to provide a simulated organ with an adjustable orifice to simulate various types of organs (see Gillio, column 7, lines 29-36).

Regarding claim 21, Matsuzaki discloses a simulated organ tract that is substantially a straight tube, such that the tactile feedback and visual feedback are substantially independent of a geometrical shape of the simulated organ tract (Col. 2, line 27).

Regarding claim 23-25 and 27, Matsuzaki discloses a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. However, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Thus, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the endoscopic simulation described in Matsuzaki, by providing a simulated endoscope comprising a tool unit. The motivation for doing so would have been to provide a more realistic simulation and to provide standard, well known components of an endoscope. Furthermore, Gillio teaches that the control unit detects the motion of simulated forceps (column 20, lines 60-65), but does not specify a detection of a roll (as per claim 25). However, it is the examiner's position that the feature of detecting up, down, and "roll" movement of a tool within an endoscope is notoriously well known.

Regarding to claim 39, Matsuzaki discloses a three-dimensional image reconstruction device for displaying segments of the organ model in real-time. Although not explicitly stated, it is the examiner's position that the use of RAM is notoriously well known.

7. **Claims 6-10, 40 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. (USPN 6,283,763 B1; hereinafter Matsuzaki) in view of Gillio (U.S. Patent No. 5,882,206), further in view of Asano et al. (U.S. Patent No. 5,956,040; hereinafter Asano).**

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The combination of Matsuzaki and Gillio discloses all of the claimed subject matter including a three-dimensional mathematical model that constructed according to a spline that determines the geometry of the mathematical model in three-dimensions. It is not explicitly disclosed that the model features a *plurality of polygons* (as per claims 6 and 40, and 45), and specifying a deformation in the simulated organ determined by altering a function (as per claim 7) and adding polygons to a portion of the function (as per claim 8). It is further not specified that the simulated organ be modeled as a straight line that can be altered through a function (as per claim 9). However, Asano teaches a simulated organ comprising polygonal geometric planes, wherein a deformation in the simulated organ determined by altering a function (column 4, lines 21-41). It is further taught that the simulated organ is modeled as a straight line that can be altered through a function (column 4, lines 21-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mathematical model of an organ described in Matsuzaki, by providing graphical enhancements taught in Asano, thereby reproducing the reality of motion of an actual organ.

Regarding claim 10, Matsuzaki discloses a three-dimensional image reconstructing device and an approach data presenting device for showing an approach of a medical instrument toward a region of interest, but does not explicitly disclose that the selection of images is according to at least one previous movement. However, Gillio discloses image selection according to one previous movement of a simulated instrument within a simulated organ (column 14, lines 14-17). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the controller for selection of images described in Matsuzaki, by providing image selection according to at least one previous movement. The motivation for doing so would have been to provide real-time, accurate visual feedback.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. (USPN 6,283,763 B1; hereinafter Matsuzaki) in view of Gillio (U.S. Patent No. 5,882,206), further in view of Rosenberg (U.S. Patent No. 5,767,839).

Matsuzaki discloses a tactile feedback mechanism that is operated according to tactile feedback obtained during a medical procedure on an actual subject, but does not specify that the tactile feedback is obtained through virtual reality gloves. However, Rosenberg teaches a tactile feedback mechanism that incorporates virtual reality gloves (column 1, line 26). Hence, at the time of the invention, it would have been obvious to one of ordinary skill

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in the art at the time of the invention to modify the combination of Matsuzaki and Gillio, by providing tactile feedback through virtual reality gloves in order to provide simulated feedback for a surgical procedure.

Allowable Subject Matter

9. Patentability is seen in, although not limited to Independent claim 18.

The prior art does not fairly suggest:

- The combination of elements of simulating a three-dimensional mathematical model of a gastro-intestinal tract, divided into segments; providing a simulated endoscope having a sensor for determining the location of the sensor in the gastro-intestinal tract; *a guiding sleeve connected to the tip on an endoscope comprising a ball bearing for rolling along an inner surface of a gastro-intestinal tract*; and wherein a linear motor is attached to the guiding sleeve for providing tactile feedback by contacting the inner surface of the gastrointestinal tract.

10. Claims 19-20, 26, 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is an examiner's statement of reasons for allowance:

- As per claim 19, providing a simulated endoscope comprising a tactile feedback mechanism comprising a plurality of *inflatable rings surrounding the endoscope*.
- As per claims 26 and 41, providing a three-dimensional mathematical model of an organ for simulating a surgical procedure, wherein a loop of an endoscopic cable is simulated.

The closest prior art of record does not teach or fairly suggest this feature in the combination.

Response to Arguments

11. Applicant's arguments with respect to claims 1-27, 39-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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- Merrill (USPN 6,106,301) disclose a light wheel for blocking and unblocking light according to movement of simulated an endoscope; using a light detector to determine the movement of the simulated endoscope.
- Cover "Interactively Deformable Models for Surgery Simulation" – discloses graphical models for gastrointestinal organs.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Valencia Martin-Wallace can be reached on 703-308-4119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

CS

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July 10, 2003

Joe H. Cheng
Primary Examiner